

## REMARKS

Upon entry of this amendment, claims 19-43 will be pending. Claims 1-18 were previously cancelled. Claims 22, 26, and 33 have been amended and claims 40-43 have been newly added. Support for the amendments and new claims can be found throughout the application and in the claims as originally filed. For example, support for amended claim 22 can be found, e.g., at page 19, lines 17-19. Support for amended claim 26 can be found, e.g., at page 26, lines 12-13. Claim 33 has been amended to correct a clear typographical errors. Support for new claim 40 can be found, e.g., in original claim 22 and at page 12, lines 1-7; page 16, lines 5-9; page 16, line 20, to page 17, line 2; and page 21, lines 9-17. Support for new claim 41 can be found, e.g., in original claim 22 and at page 12, lines 1-7 and page 14, lines 15-19. Support for new claim 42 can be found, e.g., in original claim 22 and at page 9, lines 1-5. Support for new claim 43 can be found, e.g., in original claim 22 and at page 15, lines 23-28. No new matter has been added.

The claim amendments made herein have been made solely to expedite prosecution of the instant application and should not be construed as an acquiescence to any of the rejections set forth in the Office Action.

### Interview Summary

Applicants' representatives thank Examiner Swartz for his time to conduct a telephonic interview on June 17, 2008. The rejections detailed in items 5, 8, and 9 of the Office Action were discussed.

With respect to item 5, which concerns rejected claim 26, applicants proposed removing the term "pronounced" from the claim. Examiner Swartz agreed that the removal of the term "pronounced" would obviate the rejection of the claim.

With respect to item 8, which concerns rejected claims 22-36, Examiner Swartz asserted that the claims were rejected on the grounds that there is allegedly no guarantee that the B cells or sequences recited in claim 22 would have any relation to *Clostridium difficile* or a *C. difficile* antigen, and that any antibodies or antibody fragments generated using the sequences identified

using the method of claim 22 would bind a *C. difficile* antigen. Moreover, Examiner Swartz suggested that the inclusion of an *in vitro* step drawn to screening B cells, e.g., to identify B cells directed against a *C. difficile* antigen would obviate the rejection of claim 22-36. Applicants' representatives submitted that no such steps were required and that claims 22-36 were clear and definite. No conclusion was reached.

With respect to item 9, which concerns claim 33, Examiner Swartz asserted that it would not be feasible to identify sequences that are not effective to clear a *C. difficile* infection, largely because several factors, in addition to the sequence, may contribute to a patient's failure to clear an infection. Applicants have amended claim 33 herein to correct a clear typographical error. As amended, claim 33 is drawn to the identification of sequences that are effective to clear the infection.

#### Double Patenting

The Office maintained its provisional rejection of claims 19, 20, and 21 for alleged nonstatutory obviousness-type double patenting over claims 13 and 15 of copending Application No. 11/630,926. Applicants do not agree that the present rejection is proper. However, as noted by the Office, this is a provisional rejection over the co-pending application 11/630,926. Applicants note that obviousness-type double patenting would become a potential issue only if the co-pending application's claims were allowed and issued before the present claims. As it is not clear (i) which of the above applications will issue first, and (ii) what claims of what scope will be allowed in each application, it is not feasible at this time to properly assess obviousness-type double patenting. Thus, applicants respectfully request deferral of the issue until there is allowable subject matter.

#### 35 U.S.C. § 112, Second Paragraph

The Office maintained the rejection of claim 26 for alleged indefiniteness. According to the Office, "it remains indefinite what constitutes a 'pronounced' or 'strongly marked' antibody

response, and it remains unclear what level of response is deemed positive or negative to infection by *C. difficile*.” (Page 2 of the Office Action).

Applicants do not agree that claim 26 is indefinite, however, in the interest of moving the present application towards allowance, applicants have amended claim 26 by replacing the term “pronounced” with the phrase “antibody response detectable by Western blotting.” In light of this amendment, applicants request that the present rejection be reconsidered and withdrawn.

The Office also rejected claims 22-36 for alleged indefiniteness. With respect to claim 22, the Office asserted that:

While the claim does determine sequences that occur in total at a frequency of at least one percent, it is unclear how one determines that the antibodies are “specific against at least one antigen” of *C. difficile*. It appears that the method would also detect antibodies which bind to any other antigen, as long as the detected set of sequences also occur in total at a frequency of at least one percent wherein the set of sequences include a dominant sequence and sequences of at least 80% homology to the dominant sequence. (Office Action page 3).

Applicants do not agree that claim 22 is indefinite, however, for the purpose of furthering prosecution, applicants have amended claim 22 to recite a step of “(iii) confirming that an antibody comprising the dominant sequence is therapeutically effective.” It is clear that sequences identified and the antibodies generated using the method of amended claim 22 are specific against at least one antigen of *C. difficile*. Thus, the metes and bounds of claim 22 are clear and definite, as are those of claims 23-36, which ultimately depend from claim 22.

In addition, the Office rejected claim 33 for alleged indefiniteness. According to the Office, “[t]he claim recites that the method can identify antibody sequences that [sic] are ‘not effective’ to clear the infection” (Office Action, page 4). In response, applicants respectfully submit that the inclusion of the term “not” in claim 33 was a typographical error. Applicants have amended claim 33 to delete the term. As amended, claim 33 is drawn to identifying sequences that “are effective to clear the infection.” As such, claim 33 is clear and definite.

The Office also rejected claims 37-39 for alleged indefiniteness as they depend from claims rejected for alleged indefiniteness. In view of the above remarks and amendments,

applicants submit that claims 37-39 are definite as they ultimately depend from claim 22, the metes and bounds of which are clear and definite.

In view of the above amendments and remarks, applicants respectfully request reconsideration and withdrawal of the rejections of claims 22-36 under 35 U.S.C § 112, second paragraph.

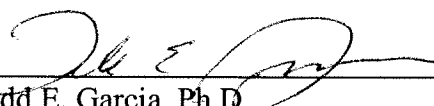
### CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, which action is respectfully requested. The fees for the petition for a three month extension of time and the Request for Continued Examination are being paid concurrently herewith on the Electronic filing system (EFS) by way of deposit account authorization. Please apply any other charges or credits to deposit account 06-1050, referencing attorney docket no. 22083-0008US1.

Respectfully submitted,

Date: \_\_\_\_\_

8/22/08

  
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